

NIBIB WORKSHOP ON BIOMEDICAL INDUSTRY RESEARCH AND TRAINING OPPORTUNITIES

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Executive Summary

A “Workshop on Biomedical Industry Research and Training Opportunities” was conducted by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) on December 16-17, 2003, at the Bethesda Hyatt Hotel in Bethesda, Maryland. This meeting represented an initial step for the NIBIB to establish communication and interaction with a broad scope of commercial biomedical companies. The overall objectives of the workshop were to explore common ground and to identify issues that might be more effectively addressed together than by the Institute or industry alone. To meet these objectives, industry participants were requested to address two questions:

1. What major problem needs to be solved or what major research advance is needed to provide significant improvement in healthcare for your industry?
2. How can the NIBIB and industry interact to (1) facilitate research and translate results to commercial and patient applications and (2) address future manpower needs?

A total of 45 people attended this workshop including invited participants from 23 biomedical companies that encompass a broad scope of healthcare applications in the areas of devices, imaging, materials, pharmaceuticals, and prosthetics. Recommendations resulting from this workshop were based on input from the industry participants.

In response to the first objective question, each industrial participant made a brief presentation that included a major problem that needs to be solved or a major research advance that will result in a significant improvement for the company’s area of interest. While there was variety in the presented problems and research needs among individual companies, there were common themes within the technical focus areas of imaging, materials and devices, pharmaceuticals, and prosthetics. Most needs fit into the general categories of multi-disciplinary collaborations and partnerships, novel technologies and approaches (especially at molecular levels), informatics and computer applications, and cost and time issues.

To address the second question, commercial participants divided into two groups in breakout sessions to make recommendations and then reconvened in a plenary session to develop a consensus list of recommendations for the workshop. In general, participants suggested that the NIBIB should primarily focus on developing new technologies and accelerating the adaptation of breakthroughs in technology to biomedical applications. Specific consensus recommendations for the NIBIB and industry from this workshop include:

- *Partnerships and collaborations* – The NIBIB should encourage and facilitate effective partnerships among academia, government, and industry to address issues such as intellectual property, multi-disciplinary and multi-organizational research and training collaborations, and compliance training. To facilitate partnerships, the NIBIB should:
 - Establish a NIBIB liaison committee consisting of representatives from a broad range of biomedical applications from industry (large and small), clinics, NIH institutes, FDA, CMS, and other federal agencies;
 - Create funding mechanisms which require industry/academia partnerships; and
 - Develop intellectual property models and analyze current practices.
- *Centers of excellence* – The NIBIB should create centers of excellence aimed at translating medical technologies to patient applications and from animal to human trials. An advisory board consisting of industry and government agency representatives should be included with each center.
- *Data and sample management* – The NIBIB and industry should collaborate to address data and sample management issues such as:
 - Bioinformatics and computational tools for managing vast and disconnected data systems,
 - Access to validated publicly-funded clinical data and samples as public resources, and
 - Technical performance standards for data acquisition and analysis technologies (e.g., imaging) and associated metrics for clinical trial endpoints.
- *Inter-disciplinary training* – Industry and the NIBIB should collaborate to support and implement inter-disciplinary training at different (rotating) industry sites. Training should be conducted at pre-doctoral, post-doctoral, and career levels.
- *Communication* – The NIBIB should develop and support activities and mechanisms aimed at showcasing emerging technologies to industry and other related groups such as the FDA. In particular, the following actions were suggested:
 - Industry and the NIBIB should cooperate to communicate problem areas or research needs in their areas of interest to investigators in academia and other research organizations, and

- The NIBIB should support targeted workshops on emerging technologies and industry needs such as imaging agents, new imaging devices, and new materials.
- *Health economics* – The NIBIB should facilitate the development of applications in the field of health economics to bioengineering and multi-disciplinary research.
- *Industry reviewers* – The NIBIB should support increasing the number of industry reviewers on NIH peer-review study sections and developing review criteria to reflect partnership issues. In turn, industry should actively pursue participation on NIH study sections.
- *Intramural program* – The NIBIB should develop and expand an intramural research program with a training component and unique research projects (i.e., research not done anywhere else).

Results of this workshop will be used as input in the planning and development of the NIBIB's research and training programs. Current plans are to post this report on the Institute's Web site.

Workshop Proceedings and Results

Background

The broad mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the newest of the research institutes at the National Institutes of Health (NIH), is to improve healthcare by supporting the development and translation of technologies that enable fundamental discoveries and facilitate disease detection, treatment, management, and prevention. This mission involves conducting and supporting focused and multi-disciplinary research and research training based on collaborations between the quantitative and biomedical sciences. As the NIBIB plans and develops its research and training programs, input from the extramural scientific community is necessary to ensure that Institute programs are relevant to biomedical research needs and national healthcare priorities, address issues and challenges associated with developing and applying enabling technologies, and support the mission of the NIH in general and the Institute in particular. Input from the biomedical industry community is especially important with regard to identifying specific research needs that will result in significant healthcare improvements, translating technologies and research results to patient applications, identifying special manpower needs, and developing effective training opportunities. To obtain this input, a "NIBIB Workshop on Biomedical Industry Research and Training Opportunities" was conducted on December 16-17, 2003, at the Bethesda Hyatt Hotel in Bethesda, Maryland.

Objectives

This meeting represented an initial step for the NIBIB to establish communication and interaction with a broad scope of commercial biomedical companies. The overall objectives of the workshop were to explore common ground and to identify issues that might be more effectively addressed together than by the Institute or industry alone. To meet these objectives, industry participants were requested to provide input on the following two questions:

1. What major problem needs to be solved or what major research advance is needed to provide a significant improvement in healthcare for your industry? The research should be something that industry currently would not or could not support as part of their research agenda.
2. How can the NIBIB and industry interact to (1) facilitate research and translate results to commercial and patient applications and (2) address future manpower needs? These issues involve identifying (1) programs or opportunities that the NIBIB can support to encourage public/private partnerships and industry/academia/federal agency interaction and (2) what industry can offer in these areas.

Program

The workshop program is included as Appendix A. An orientation dinner was held on the evening of December 16 to provide information to participants on the mission and status of the NIBIB; results of a “NIBIB Biomedical Entrepreneurial Science Working Group Meeting” held on August 1, 2003 (http://www.nibib1.nih.gov/events/BESWG/BESWG_ExecSumm.pdf); and the workshop program and objectives. On the morning of December 17, industry participants were divided into two groups (one with strong imaging and chemistry representation and the other with strong representation from the devices, pharmaceuticals, prosthetics, and materials industries) to address question one on major problems that need to be solved or research advances that are necessary to provide a significant improvement in healthcare. Industry participants made five-minute presentations that provided an overview of their company and presented a critical problem or research need. Information was recorded and discussed with NIBIB program staff with interests in the technical areas represented by the two groups.

The groups then met in a plenary session to hear a presentation on “Perspectives on Federal Government/Biomedical Industry Interactions” by Dr. John Linehan, Vice President of Bioengineering for the Whitaker Foundation. The presentation provided an overview of the biomedical engineering field, presented perspectives on the NIBIB and its value to industry and multi-disciplinary science, and set the stage for the question two discussions.

Following the plenary presentation, industry participants divided into the same two groups to address question two on NIBIB/industry interactions in research and training. After preparing lists of specific recommendations for NIBIB and industry interactions, the groups met in a final plenary session to develop a consensus list of recommendations for the workshop.

Participants

A total of about 45 people attended this meeting including industry representatives, NIBIB scientific and administrative staff, staff from other federal agencies, and representatives from technical societies and foundations. Industry participants consisted of invited representatives from 23 biomedical companies that encompass a broad scope of healthcare applications including devices, imaging, materials, pharmaceuticals, and prosthetics. Total annual sales of these companies exceed \$100 billion. Other federal agency representatives were from the Department of Energy and the National Science Foundation. Society and foundation participants were from the Academy of Radiological Research and the Whitaker Foundation. A list of workshop participants is given in Appendix B.

Major Problems and Research Advances for Significant Healthcare Improvements

In response to the first objective question, each industrial participant made a brief presentation that included a major problem that needs to be solved or a major research advance that will result in a significant improvement for the company's area of interest. While there was variety in the presented problems and research needs among individual companies, there were common themes within the technical focus areas of imaging, materials and devices, pharmaceuticals, and prosthetics. Most needs fit into the general categories of multi-disciplinary collaborations and partnerships, novel technologies and approaches (especially at molecular levels), informatics and computer applications, and cost and time issues.

Specific research needs and problems for the industrial focus areas represented at this workshop are given in the following text. Suggestions from individual presentations with similar themes have been combined in some cases.

Biomedical Imaging

- *Novel diagnostic imaging technologies* - This item involves identifying new basic science approaches to biomedical imaging including fundamental modalities, chemical and physical contrast mechanisms, and data processing and display techniques. The novel technologies should be aimed at improving resolution

(spatial, temporal, and contrast) and improving detection capabilities and physiological performance of chemical agents.

- *Detection and observation of in-vivo abnormalities at molecular levels* – Detection and characterization of disease at genesis and well before clinically-observable manifestations will enable more effective interventions. Imaging at molecular levels will enable direct assessment of treatment effects and progression, and better understanding of basic disease and treatment processes. Fusion approaches applied to cellular/molecular-level *in vivo* imaging will enable investigators to follow a compound throughout a performance study without compromising the health of the animal or patient. More effective application of imaging to drug development and testing is an important problem that needs to be addressed for drug and imaging companies.
- *Non-invasive methods for guiding therapy and assessing outcomes* - Developing technologies and procedures for real-time, image-guided diagnosis and therapy will enable effective treatment at early stages of disease. This includes integrating imaging and pharmaceutical development and testing.
- *In-vivo, real-time pathology* – Techniques are needed for real-time tissue diagnosis that, for example, can define tumor nuclear grade, level of activity, and degree of invasion at the cellular and connective tissue levels. This item includes image-guided, reliable sampling capability.
- *Access to validated clinical data and samples* – Broad access to validated clinical data related to biomedical imaging will facilitate research and clinical studies.
- *Reduce long times to translate research results to practice* – Programs are needed to encourage multi-site, multi-disciplinary collaborations in research and education; and collaborations among federal, academic, clinical, and industrial research programs. These programs should be aimed at reducing the time spent in the “translational” research phase and decreasing the typical long times required for adoption of new techniques by the medical community.
- *Low-cost equipment and procedures* – In view of the current healthcare climate characterized by rising healthcare costs and reimbursement concerns, programs that support the development of low-cost equipment and procedures are essential to address national priorities.

Materials and Devices

- ***Integrating the physical, life, and information sciences to create advances in healthcare*** - There are many examples of biomedical advances resulting from multidisciplinary and collaborative research that have produced significant advances in healthcare. Effective programs to encourage and support these efforts are necessary. In addition to inter-disciplinary collaboration, cooperative efforts

among academia, industry, federal agencies, and clinical organizations need to be developed and supported. These interactions should be partly aimed at (1) developing efficient processes for dealing with regulatory and reimbursement issues and (2) streamlining biomedical research and development.

- *Smart and biomimetic sensors and devices* - Sensors and devices that can adapt to a variety of physiological environments, perform a variety of operations, and be implanted without biofouling or rejection complications are needed for *in vivo* monitoring and therapeutic action. This includes non-invasive methods (i.e., sensors, imaging systems) for guiding therapy and assessing outcomes for new drugs and devices.
- *Commercially-viable methods for delivering tissue-engineered products to patients* – Cost-effective methods to commercialize tissue-engineered products are needed to ensure broad availability to the patient community. Addressing this issue will require collaboration between chemists, bioengineers, and biologists at the molecular level.
- *Non-invasive methods for validating clinical results* – Efficient validation of clinical results is necessary for timely assessment and release of products to patients. Better methods – especially non-invasive – will facilitate these activities.
- *Focus on design innovation* – Programs that support and encourage progress in therapeutic medical devices based on design innovation as opposed to materials or functionality approaches will offer novel approaches to medical applications.
- *Virtual healthcare communities* – Technological research and development aimed at developing biosensors, remote diagnostics, remote therapeutics, and connecting clinicians with design engineers, bioengineers, and health economists will provide a virtual healthcare community that can effectively and efficiently address individual patient and method development issues.
- *Measurement and control of material surface chemistry* – To improve device performance and reduce morbidity related to use, research is needed to understand surface chemistry especially related to biofouling and inorganic/organic interface effects. The importance of the field of chemistry was emphasized in several industrial focus areas.

Pharmaceuticals

- *Cost and time of drug development and deployment* – A general problem identified by many of the pharmaceutical representatives was the need to reduce the cost and time of bringing new drugs to the clinic. Areas that need to be addressed include streamlining multi-disciplinary and multi-organizational research and development, developing molecular-level imaging technologies to

better define and follow the actions of pharmaceutical agents, and facilitating academic/industry/regulatory agency interactions all along the research/development/commercialization path.

- *Bioinformatic and computational tools for data management* – In general, the development of new bioinformatic and computational tools for integrating and managing vast amounts of data from disconnected systems is necessary to facilitate scientific decisions and healthcare advances. Specifically, this involves (1) integrating data and extracting useful information and (2) integrating the biological, physical, and information sciences. Development of these tools will address current problems involving (1) the rapid increase of candidate targets and poor knowledge of biological impacts or therapeutic relevance and (2) the mismatch between the rapidly increasing rate of data production and the relatively slow rate of increase in data management and interpretation capabilities.
- *Access to validated clinical data and samples* – Better access to validated clinical samples as a public resource is needed for the diagnosis and genetic characterization of disease. This access will facilitate the development of correlations between phenotypes, DNA variations, and imaging modalities.
- *Novel drug delivery methods* – Advances in the areas of macromolecules, closed-loop delivery, and targeted delivery are needed to more effectively and efficiently deliver pharmaceuticals to the disease location and to minimize effects on healthy tissues.
- *Translation of animal research to human applications* – The development of improved techniques for translating results of animal research to human applications is a recognized need in the biomedical research community.
- *Risk stratification at the population, patient, and tissue/organ levels* – This item involves (1) developing methods for non-invasive assessment of diseases and related components, (2) identifying appropriate disease markers, and (3) establishing correlations between markers and long-term outcomes to determine surrogate markers. These activities will enable a shift from reactive to proactive medicine and will provide reliable indicators for estimating therapeutic results without having to follow trials to their ultimate endpoints.

Prosthetics

- *Analytical and experimental tools for prosthetic analysis and prediction* – Analytical and experimental tools are needed to predict kinematics, stress, and wear for existing implants and biology-based solutions. These tools are especially needed for cartilage, tendon, and spinal disc repair, regeneration, and replacement. Applications include following repair and degree of healing, determining location and timing of replacement implant, and facilitating research concerning basic causes and mechanisms of implant degradation and failure.

Benefits of the application of these tools include (1) prevention of pain and loss of lifestyle through early intervention and (2) significant saving in healthcare costs.

- *Integration of biology-based treatments and engineering mechanics* – Research is needed to understand the viability and durability of cells, and soft tissue repair and replacement in the *in vivo* mechanical environment. This research would support the development of analytical tools for prosthetic analysis.
- *Self-correcting devices* – The development of self-correcting prosthetic devices and implants that improve function and lower metabolic costs is a critical need for this industry.
- *Aging population issues* – As the average age of the population continues to increase, special problems related to longer-term *in vivo* exposure, changing shape and chemical composition of the host body, long-term biocompatibility, and material degradation need to be addressed by focused research programs. Associated with the aging issue is the need for more trained clinicians and technicians who can adjust and evaluate implants and prosthetics for an increasing number of aging citizens.

Recommendations for NIBIB and Industry

The second objective was aimed at addressing what the NIBIB and industry can do to (1) facilitate research and translation of results to the healthcare community and (2) address future manpower needs. Commercial participants first divided into two groups in breakout sessions to make recommendations and then reconvened in a plenary session to develop a consensus list of recommendations for the workshop. In general, participants suggested that the NIBIB should primarily focus on developing new technologies and accelerating the adaptation of breakthroughs in technology to biomedical applications.

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Summary

This workshop represents a first step for the NIBIB to establish communication and collaboration with the biomedical industry. For the Institute to effectively accelerate the adaptation of breakthroughs in technology to clinical use, this cooperation is very

important. The wide range of biomedical industries represented at this workshop was appropriate considering the broad scope of the NIBIB's research and training portfolios. Results of this meeting will be considered by the Institute in its program planning and development. Current plans are to post this report on the NIBIB Web site.

Acknowledgements

The authors gratefully acknowledge the efforts of the Workshop Steering Committee in developing the agenda and list of participants. Members of the Steering Committee included Dr's. Rebecca Bergman (Medtronic), Arthur Coury (Genzyme), Bijan Dorri (General Electric), Robert Nerem (NIBIB and Georgia Tech), and Stephen Williams (Pfizer). The contributions of Dr's. Joseph Fritz (Toshiba), Elizabeth Galbreath (Eli Lilly), Todd Johnson (Zimmer), and Joel Lazewatsky (Bristol-Myers Squibb) as session moderators are also gratefully recognized. A sincere thanks is extended to Dr. John Linehan of the Whitaker Foundation who provided an excellent presentation to set the stage for discussions concerning recommendations for NIBIB and industry interactions. The important contributions of NIBIB staff members Dr's. John Haller, William Heetderks, Christine Kelley, Peter Kirchner, Meredith Temple-O'Connor, and Patricia Sokolove as session moderators and technical resources are also acknowledged.

END

APPENDIX A

AGENDA FOR THE NIBIB WORKSHOP ON BIOMEDICAL INDUSTRY RESEARCH AND TRAINING OPPORTUNITIES

TUESDAY, DECEMBER 16

Congressional Room

- 5:00 PM **Reception**
- 6:00 PM **Orientation Dinner**
- 7:15 PM **Welcome and Charge**
Roderic Pettigrew, Director NIBIB
- 7:30 PM **Results of NIBIB Entrepreneurial Science Working Group**
Christine Kelley, NIH/NIBIB
- 7:45 PM **Workshop Agenda and Format**
Richard Swaja, NIH/NIBIB
- 8:00 PM **Adjourn**

WEDNESDAY, DECEMBER 17

- 7:30 AM **Continental Breakfast** *Lalique Room*
- 8:00 AM **Welcome**
Roderic Pettigrew, Director NIBIB
- 8:05 AM **Objectives and Agenda**
Richard Swaja, NIH/NIBIB
- 8:15 AM Concurrent Sessions: *Lalique & Waterford Rooms*
Industry Needs for Significant Healthcare Improvements
- 9:30 AM Break
- 10:00 AM Plenary Session: *Lalique Room*
Perspectives on Federal Government/Biomedical Industry Interactions
John Linehan, Whitaker Foundation

- 10:20 AM Breakout Groups: *Lalique & Waterford Rooms*
Issues and Challenges for Addressing Research and Manpower Needs
- 11:45 AM Lunch Served
- 12:00 PM Working Lunch: Breakout Groups Continue
**Recommendations for NIBIB & Industry Activities to Address Issues
& Challenges**
- 1:00 PM Break
- 1:30 PM Plenary Session: *Lalique Room*
Breakout Session Reports and Development of Recommendations
- 3:00 PM Adjourn

APPENDIX B

PARTICIPANTS IN THE NIBIB WORKSHOP ON BIOMEDICAL INDUSTRY RESEARCH AND TRAINING OPPORTUNITIES

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Richard Swaja
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END